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10/034,266	10/19/2001	David M. Griffiths	VI/99-004.D	9517

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EXAMINER

IMAM, ALI M

ART UNIT

PAPER NUMBER

3737

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,266

Applicant(s)

GRIFFITHS ET AL.

Examiner

Ali Imam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10 and 12-21 is/are rejected.
- 7) ☒ Claim(s) 9 and 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10-19-01
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. In response to the amendment filed 6/28/4, all necessary changes to the claims have been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no explanation in the specification nor the disclosure supports for the added limitation "controlling at least one parameter during preparation of the medium". The disclosure mentions about controlling parameters during delivery but does not mention about controlling parameters during preparation of the medium.

Response to Arguments

4. Applicant's arguments filed 6/28/4 have been fully considered but they are not persuasive.
5. In regard to the double patenting rejection, examiner agrees that the instant application is a divisional application but it is not clear how the pending claims appear in the issued patent (US

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6,317,623). A divisional case should not include any claims that are already examined in the parent case. Therefore, the examiner maintains the double patenting rejection.

6. With respect to the patentable subject matter, the applicant's core argument is that the prior arts of record (as applied in the prior office action) alone or in combination teaches or suggests measuring a property of the contrast agents during preparation or delivery.. The examiner respectfully disagrees. Giddey teaches in col. 10, lines 13-37, a method of preparing contrast agents (gas-filled microspheres) comprising the step measuring the concentration or size of the contrast agents in order to assist in properly preparing the contrast agents. Cheung teaches in col. 5, lines 4-54 or Guberek teaches in col. 5, lines 5-25 or Orsolini teaches in col. 4, lines 26-35, a method of preparing contrast agents comprising the step of measuring the size of the contrast agents.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

8. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

9. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 6-8, 12, 15, 16, 20, and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 44 (regarding claim 1), 70

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(regarding claims 6-8), 39 (regarding claims 12, 15, 16), and 25 (regarding claims 20,21) of U.S. Patent No. 6,317,623. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is obvious to an ordinary skill in the art that concentration is a property of a contrast enhancement agent. Furthermore, the claims of the instant application is broader in scope than the claims of the '623 patent.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-5 and 15-19 rejected under 35 U.S.C. 102(b) as being anticipated by *Giddey et al.* (US 5,310,540).

13. *Giddey* teaches in col. 10, lines 13-37, a method of preparing contrast agents (gas-filled microspheres) comprising the step measuring the concentration or size of the contrast agents in order to assist in properly preparing the contrast agents. *Giddey* further teaches the pressurizing and agitating steps (col. 9, lines 22-39). *Giddey* continues to teach the steps controlling the size distribution and concentration of the contrast agents (col. 9, line 36 and col. 11, line 54).

Giddey's contrast agent is used for ultrasonic diagnostic imaging system which inherently suggests the step of imaging a patient.

14. Claims 1, 5, 15, 18, and 19 are further rejected under 35 U.S.C. 102(b) as being anticipated by *Cheung* (US 5,194,300) or *Guberek et al.* (US 5,230,343) or *Orsolini et al.* (US

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5,445,832). Cheung teaches in col. 5, lines 4-54 or Guberek teaches in col. 5, lines 5-25 or Orsolini teaches in col. 4, lines 26-35, a method of preparing contrast agents comprising the step of measuring the size of the contrast agents.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans, III et al. (US 5,885,216) in view of Giddey et al.

Evans teaches a container (10) and a sensor adapted to measure concentration of the contrast agent but fails to mention specifically an agitation mechanism.

Giddey teaches in col. 9, lines 17-35, an agitation mechanism specifically used in preparation of ultrasonic contrast agents in order to agitate the contrast agents so that intended concentration of the contrast agents is achieved.

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Therefore, it would have been obvious to an ordinary skill in the art at the time the invention was made to use the agitation mechanism of Giddey in the contrast agent preparation process of Evans so that intended concentration of the contrast agents is achieved.

Allowable Subject Matter

18. Claims 9 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: none of the prior art, alone or in combination teaches or suggests the specific control mechanism in combination with the processing unit to control the agitation mechanism.

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Imam whose telephone number is 703-305-0028. The examiner can normally be reached on Mon. - Th., 8:00- 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Ali Imam
Primary Examiner
Art Unit 3737

AMI
10/1/4